K101324

GE Healthcare
Special 510(k) Premarket Notification
GE EchoPAC BT10 Review station
May 10, 2010

510(k) Summary

OCT 5 2010

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 10, 2010
Submitter:	GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics. LLC. 9900 Innovation Drive Wauwatosa, WI, USA 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics. LLC. Phone: (414) 721-4214 Fax: (414) 918-8275
Secondary Contact Person:	Jim Turner Regulatory Affairs Manager GE Healthcare Phone: (262) 544-3359 Fax: (414) 908-9225
Device: Trade Name:	GE EchoPAC BT10
Common/Usual Name:	Workstation Software for ultrasound image review, analysis and reporting
Classification Names:	21 CFR 892.2050
Product Code:	LLZ
Predicate Device(s):	K072952 - GE EchoPAC K081921 – GE Vivid E9 K092079 - GE Vivid S5/S6
Device Description:	GE EchoPAC provides image processing, annotation, analysis, measurement, report generation, communication, storage and retrieval of ultrasound images that are acquired via GE Vivid family of ultrasound scanners, primarily for cardiology ultrasound applications but also for general imaging. The EchoPAC software is an integral component of each Vivid system, providing the post acquisition image management and reporting functions of the scanner. Sold as a stand-alone software only product it can be installation on the customer's PC hardware, or as a plug-in to third party PACS. EchoPAC is DICOM compliant, transferring images and data via LAN between scanners, hard copy devices, file servers and other workstations. The modified or added software features for GE EchoPAC BT10 are substantially equivalent to the unmodified device and functionality cleared on GE Vivid E9 and GE Vivid S5/S6.

Intended Use: The GE EchoPAC workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

Technology: The EchoPAC BT10 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates, including conformance to DICOM standard.

Summary of Clinical Tests:

The subject of this premarket submission, EchoPAC BT10, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the EchoPAC BT10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Vingmed Ultrasound AS
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W Innovation Dr., RP-2138
WAUWATOSA WI 53226

OCT 5 2010

Re: K101324
Trade/Device Name: GE EchoPAC BT10
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 27, 2010
Received: August 30, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number:

Device Name: GE EchoPAC BT10

Indications for Use:

The GE EchoPAC BT10 workstation is indicated for diagnostic review and analysis of ultrasound images acquired under various modes of operation including B, M, Color M modes, Color, Power, Pulsed & CW Doppler modes, Coded Pulse, Harmonic and Realtime 3D. Clinical applications include: Fetal; Abdominal; Urology (including prostate); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic, & vascular).

Prescription Use: YES AND/OR Over-The-Counter Use: NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark D. Olham for David G. Brown
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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